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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/460,324	12/10/1999	KENNETH J. KASHA	411044.9002	2350

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EXAMINER
GRUNBERG, ANNE MARIE

ART UNIT	PAPER NUMBER
1661	

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13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/460,324	Applicant(s) Kenneth J. Kasha et al.
	Examiner Anne Marie Grunberg	Art Unit 1661

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jan 27, 2003* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-21, 25-27, and 31-33* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-21, 25-27, and 31-33* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Notice of References Cited	Application/Control No. 09/460,324	Applicant(s)/Patent Under Reexam Kenneth J. Kasha et al.	
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U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY[1]	Name	Classification[2]	
x	A	5,445,961	8/1995	Genovesi et al.	435	240.5
x	B	5,610,042	3/1997	Chang et al.	435	172.3
	C					
	D					
	E					
	F					
	G					
	H					
	I					
	J					
	K					
	L					
	M					

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY[1]	Country	Name	Classification[2]	
x	N	EP 0 455 597	6/1991	Europe	Kreuger	C12N	5/00
	O						
	P						
	Q						
	R						
	S						
	T						

NON-PATENT DOCUMENTS

*		Include, as applicable: Author, Title, Date, Publisher, Edition or Volume, Pertinent Pages
x	U	Hu et al., Plant Cell Reports, (1997), 16:520-525
	V	
	W	
	X	

* A copy of this reference is not being furnished with this Office action. See MPEP § 707.05(a). [1] Dates in MM-YYYY format are publication dates. [2] Classifications may be U.S. or foreign.

DETAILED ACTION

1. The finality of the last Office action is withdrawn.

2. Claims 1-21, 25-27, and 31-33 are pending.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 4, 5, 32 and dependent claim 6, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4 and 5 are vague and indefinite due to the recitation "of induction medium" at the end of the sentence. This phrase should be deleted as it is confusing.

Claim 4 is also vague and indefinite in the recitation of "a said arabinogalactan protein". The word "said" refers to a specific protein, whereas the word "a" is not a specific article. The deletion of "a" would obviate this rejection.

Claim 32, step (d) is vague and indefinite as it is unclear to what "15%" is referring. The insertion of --viable microspores after a 10 day incubation period-- at the end of the sentence would obviate this rejection.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-14, 18-21 and 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Genovesi et al. in view of Kreuger et al (EP 0 455 597).

Claims 1-14, 18-21 and 31-33 are drawn to a method of producing an embryo wherein a microspore-containing segment from a donor plant is harvested and incubated in pre-treatment conditions at a temperature from about 3°C to about 6°C such that a substantial portion (50-100%) of microspores are maintained at a uninucleate cell cycle G1 phase. Microspores are then isolated from the segment and incubated in an induction medium comprising arabinogalactan to induce embryogenesis and thereby produce embryos. The donor plant may be a cereal, such as wheat or barley. The arabinogalactan may be present in the induction medium in an amount ranging from 1 mg/liter - 100 mg/liter, or from 10 mg/liter - 25 mg/liter and may be present for about two weeks. The pre-treatment conditions may include a temperature between 3-10°C for 3-10 days wherein incubation occurs in an aqueous solution containing 0.2-1.0 mol/liter sugar alcohol such as mannitol. The incubation may also occur in the aqueous medium for 7 to 28 days at a temperature of 3-10°C. The induction treatment may be from 3-14 days and may contain an auxin such as phenylacetic acid. Plant regeneration from the embryos may also occur. The embryos may also be placed on a support such as filter paper. The microspore containing segment may be blended or vortexed in an aqueous solution of about 0.2 mol/liter to about 1.0 mol/liter sugar alcohol.

Genovesi et al teach a method of producing an embryo wherein a microspore-containing plant segment is harvested from a donor plant and incubated under pre-treatment conditions wherein a substantial portion of microspores are maintained at a uninucleate cell cycle G1 phase (column 4, lines 20-24, 66-68; column 5, lines 5-8, for example). The microspores are isolated

from the segment and incubated in an induction medium to induce embryogenesis (column 4, lines 34-35; column 6, lines 52-55; for example), thereby producing embryos (column 8, lines 6-9, 24-25, 43, 52; for example). Genovesi et al teach the method wherein the donor plant is a cereal plant such as barley (column 4, line 3). Although Genovesi et al do not specifically teach that a substantial portion of microspores at a uninucleate cell cycle G1 phase comprises from 50-100%, this would appear to be the case because of the stress treatments, ie mannitol and cold treatments (column 4, lines 20-24; column 19, lines 14-24, for example). The pre-treatment conditions may comprise a temperature of from about 4-25°C for 1 to 14 days and incubation in an aqueous solution having from about 0.2 mol/liter to about 1.0 mol/liter sugar alcohol (column 5, lines 9-14, 33-35, 53-64, for example). The temperature range as well as the incubation duration taught in Genovesi et al encompass that claimed by Applicant. Mannitol is described at column 5, lines 55-62, for example). The pre-treatment conditions include an aqueous solution (column 24, lines 20-32, for example) and as such, the incubation occurred in water. Tassels and/or anthers are described in column 4, line 21; and column 28, line 40, for example. Genovesi teach microspores incubated in induction medium for about twelve days (column 8, lines 35-38). Although the auxin phenylacetic acid is not specifically taught by Genovesi et al, other auxins such as 2,4-D, NAA, dicamba are taught at column 17, lines 10-40, for example. At column 17, lines 10-40, Genovesi et al teach that there is no consensus on a requirement for a particular hormone at a particular stage. Plant regeneration from embryos is taught at column 21, lines 51-66, for instance. Although Genovesi et al do not specifically mention filter paper, they

do teach a support such as a nylon mesh raft for the growth of calli/embryoids (column 23, lines 24-32). At column 7, lines 23-68, for example, the benefits of floating the developing microspores and embryos on a liquid medium using some type of solid support are described. The microspore containing segment is blended or vortexed as described for example at column 6, lines 15-20, and was precultured in an aqueous solution of about 0.2 mol/liter to about 1.0 mol/liter sugar alcohol (column 5, lines 53-68; column 6, lines 12-26; for example).

Genovesi et al do not teach arabinogalactan to induce embryogenesis.

Kreuger et al teach arabinogalactan to induce embryogenesis (column 3, lines 14-18). They teach a range of 0.01 to 100 mg/liter at column 3, line 12. However, they teach at lines 14-18 that 0.1-20 mg/liter or 1-10 mg/liter are preferred for embryogenesis induction. At column 6, line 22, they teach 18 days of culture in arabinogalactan containing medium.

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to utilize the method of producing an embryo as taught by Genovesi et al and to modify it to include the addition of arabinogalactan as taught by Kreuger et al given the dramatic stimulation in embryogenic growth with the use of arabinogalactan as reported by Kreuger et al. Kreuger et al state in column 2, lines 30-32, that the method (of using arabinogalactan in tissue culture processes) is "generally applicable, including for anther and microspore cultures."

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to utilize the method of microspore culture as taught by Kreuger et al and to modify it to include cereal plants as taught by Genovesi et al or Hu et al, given that cereals are the most important agronomic crop and both Hu et al and Genovesi et al teach improved functional methods of cereal microspore culture and subsequent cereal regeneration.

7. Claims 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Genovesi et al and Kreuger et al in view of Chang et al

Claims 25-27 are drawn to a method of introducing a gene of interest into a microspore wherein a genetic construct with a gene of interest is introduced into the microspore obtained as in claim 1. Particle bombardment or *Agrobacterium* mediated transformation may be used.

Genovesi et al and Kreuger et al have been discussed *supra*.

Genovesi et al and Kreuger et al do not teach genetic transformation.

Chang et al teach genetic transformation using particle bombardment of microspores (column 2, lines 12-19, for example). Official notice is given that *Agrobacterium* mediated transformation would be obvious to use on dicots susceptible to infection as alluded to by Chang et al in column 1, lines 30-33.

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to utilize the method of microspore culture as taught by Genovesi et al and Kreuger et al and to include transformation procedures as taught by Chang et al or as is well-

known in the art, given that transformation of plants is desirable in order to implant disease resistance, for example, into a cultivar. Genovesi et al teach also teach transformation of microspores in one embodiment (column 5, lines 47-52).

8. Claims 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hu et al in view of Kreuger et al and Genovesi et al.

Claims 13-17 are drawn to a method of producing an embryo wherein a microspore-containing segment from a donor plant is harvested and incubated in pre-treatment conditions such that a substantial portion of microspores are maintained at a uninucleate cell cycle G1 phase. Microspores are then isolated from the segment and incubated in an induction medium comprising arabinogalactan to induce embryogenesis and thereby produce embryos. The induction medium comprises an auxin and may be phenylacetic acid. Glutamine, from about 500 to about 1000 mg/L, may be present in the induction medium. The induction medium may also comprise ovary co-culture and the microspore(s) may be obtained from wheat.

Hu et al teach method of producing a wheat embryo wherein a microspore-containing segment from a donor plant is harvested and incubated in pre-treatment conditions such that a substantial portion of microspores are maintained at a uninucleate cell cycle G1 phase (page 521, column 1, lines 8-13, for example). Microspores are then isolated from the segment (page 521, column 1, lines 13-15) and incubated in an induction medium to induce embryogenesis and thereby produce embryos (page 521, column 1, paragraph under "Culture media"). The induction

medium comprises an auxin and may be phenylacetic acid (page 521, Table 1). Glutamine, from about 500 to about 1000 mg/L, may be present in the induction medium (page 521, Table 1). The induction medium may also comprise ovary co-culture (page 521, column 2, paragraph under "Ovary co-culture).

Hu et al do not teach arabinogalactan in the induction medium nor do they teach a pretreatment temperature between 3 and 6 °C.

Kreuger et al teach arabinogalactan to induce embryogenesis (column 3, lines 14-18).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to utilize the method of producing an embryo as taught by Hu et al and to modify it to include the addition of arabinogalactan as taught by Kreuger et al given the dramatic stimulation in embryogenic growth with the use of arabinogalactan as reported by Kreuger et al. Kreuger et al state in column 2, lines 30-32, that the method (of using arabinogalactan in tissue culture processes) is "generally applicable, including for anther and microspore cultures."

Summary

No claims are allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne Marie Grünberg whose telephone number is (703) 305-0805. The examiner can normally be reached from Monday through Thursday from 7:30 until 5:00, and every other Friday from 7:30 until 4:00.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached at (703) 308-4205. The fax number for the unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

ANNE MARIE GRUNBERG
PATENT EXAMINER